K043561

DEC 2 9 2004

VERTE-STACK™ Spinal System
510(k) Summary
December 2004

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Richard W. Treharne, PhD**
Sr. Vice President Regulatory Affairs

II. **Proprietary Trade Name: VERTE-STACK™ Spinal System**

III. **Classification Name: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)**

III. **Product Description**

The VERTE-STACK™ device is a stackable spacer, which inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. The construct is not intended to be employed as a stand-alone device. The VERTE-STACK™ device is fabricated and manufactured from titanium alloy. Alternatively the device may be manufactured from POLYETHERETHERKETONE (PEEK OPTIMA LT) and includes a tantalum marker.

The design of the VERTE-STACK™ device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient anatomy.

The VERTE-STACK™ device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK™ Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK™ constructs manufactured with PEEK may be used with stainless steel or titanium supplemental fixation devices. Titanium VERTE-STACK™ constructs may not be used with stainless steel supplemental fixation devices.

The purpose of this submission is to offer a titanium version of the previously cleared VERTE-STACK™ Spinal System components.

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IV. Indications

The VERTE-STACK™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK™ Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK™ device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, the Titanium DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, the Titanium TSRH® Spinal System, the Titanium CD HORIZON® Spinal System or the Titanium GDLH® Spinal System. Additionally, the VERTE-STACK™ device is intended to be used with bone graft.

V. Substantial Equivalence

Documentation was provided which demonstrated the VERTE-STACK™ Spinal System to be substantially equivalent to the previously cleared VERTE-STACK™ Spinal System components found in K041556 and K040422.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2004

Richard W. Treharne, PhD
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K043561
Trade/Device Name: Medtronic Sofamor Danek VERTRE-STACK™ Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 22, 2004
Received: December 27, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043561

510(k) Number (if known):_____

Device Name: VERTE-STACK™ Spinal System

Indications for Use

The VERTE-STACK™ Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK™ Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK™ device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, the Titanium DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, the Titanium TSRH® Spinal System, the Titanium CD HORIZON® Spinal System or the Titanium GDLH® Spinal System. Additionally, the VERTE-STACK™ device is intended to be used with bone graft.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043561